REMARKS

PRELIIMINARY REMARKS

Claims 1, 3-7, 9, 10, 20-23, 26 and 28-32 are pending and are currently rejected. Of these, claim 7 is now canceled. Claims 1 and 20-23 are amended herein, as discussed with the Examiner during the interview summarized below.

Additionally, claim 1 is amended in the second line by the insertion of "having an outside diameter and" in order to provide necessary antecedent basis for subsequent reference to the outside diameter of the PTFE tube (also by amendment herein).

The Examiner kindly granted an interview with regard to the present application, for which the applicants express their appreciation. This telephonic interview occurred on 15 March, 2011. The Examiner's Interview Summary was mailed on 21 March, 2011.

SUBSTANCE OF THE EXAMINER INTERVIEW OF 15 MARCH, 2011

Applicants are in general agreement with the Examiner's Interview Summary.

During the interview, applicants proposed amending claims 20-23 to depend from claim 1 in order to correct an error in dependency. Applicants also proposed to add a clause in each of claims 20-23 that the device is "adapted for use as an intraluminal graft" in order to provide necessary antecedent basis that was lost when the claim 19 from which these claim depended was canceled. It was proposed to add the phrase "is adapted to cover" to replace the word - -covers- - in claim 30. All of these amendments were found acceptable by the Examiner. In claim 1, applicants proposed changing the transitional phrase from "comprising" to "consisting essentially of" along with removing the limitation "essentially". The Examiner was in agreement that this amendment would overcome the Tu reference (US Patent 5,061,276). Applicants also proposed adding the word "tubular" to precede the word covering in line 2 of claim 1 (line 3 of claim 1 as shown amended above) and to then cancel claim 7. They also proposed adding a product-by process limitation to claim 1, "wherein the tubular covering is initially manufactured at a diameter larger than the outside diameter of the PTFE tube" (the phrase "tubular covering" describing a covering made of porous PTFE film per the language of the claim). The

Examiner stated that these changes may overcome the Myers et al. reference upon further consideration.

CLAIM OBJECTIONS

The Examiner has objected to claims 20-23 as being of improper dependent form for failing to further limit the subject matter of a previous claim. This has been corrected as described above.

REJECTION UNDER 35 U.S.C. §101

Claim 30 is rejected because the claimed invention is directed to non-statutory subject matter. Claim 30 has been amended to the Examiner's satisfaction, as described above.

REJECTIONS UNDER 37 U.S.C. §102

I. Claims 1, 3-7, 9, 10, 20, 23, 26 and 28-30 are rejected under 35 U.S.C. §102(e) as being anticipated by Myers et al. (US 5,628,782).

Myers et al. teach the construction of a tubular vascular graft intended for use with dialysis patients; the vascular graft is preferably made of ePTFE and includes a covering of material in a form to inhibit bleeding following removal of a dialysis needle after the tube has been punctured with the needle.

The Examiner asserts that the claimed physical property of the tube (in this case, a substantially unchanged second circumference upon expansion 100%) is present in Myers et al. even though not explicitly recited. He adds that "Since the material of the tube is the same as what is being claimed, the blood liner inherently possesses the same unchanged second circumference in response to internal pressure as the Applicant's claimed blood liner tube."

Applicants have argued previously that while their materials are the same as taught in Myers et al. (porous PTFE), the graft is engineered to have entirely different properties by using the materials differently. The tubular graft of Myers et al. does not have the

capability of increasing in circumference in response to the application of internal pressure up to a second circumference that is 100% larger than the original circumference prior to pressurization, thereafter the second circumference remaining substantially unchanged with further increasing internal pressure if used within a designed range of operating pressures.

W. L. Gore & Associates offer a commercially available vascular access graft made generally as taught by Myers et al., more specifically as generally described by Figures 13 and 14 of Myers et al. The product is sold as the GORE DIASTAT® Vascular Access Graft and is intended for dialysis applications. It is generally manufactured by the wrapping two different types of fibers around an ePTFE tubular graft that has been reinforced with helically wrapped ePTFE film prior to adding the fiber reinforcement, with the fiber reinforcement then overwrapped with additional ePTFE film. The fiber material is secured only by the outer wrapping of ePTFE film and is capable of moving aside when a dialysis needle is inserted through the graft wall, and moving back when the needle is removed, thereby reducing the amount of bleeding that occurs when the needle is removed. The mechanical effect of the various layers of fibers and film wrapped around the substrate ePTFE tube is to render the tube extremely resistant to circumferential dilatation under increasing pressure.

The Declaration of Marc Schlaud is appended herewith. Mr. Schlaud is a quality engineer with W. L. Gore & Associates that is tasked with quality assurance testing of vascular grafts. He was requested to test samples of the GORE DIASTAT® Vascular Access Graft (nominal inside diameter 6mm) by measuring graft diameter in response to increasing internal pressure. As described in his declaration, subjecting three samples of this commercially available product generally resulted in a change from an initial outside diameter of about 8.4mm at 0-10psi initial internal water pressure to an outside diameter of 8.5mm when the internal water pressure was steadily increased to 450 psi. There was no failure of any of these samples at this maximum test pressure. The resulting change in diameter was about 1%, far from the 100% required by the present claims. The 450 psi test pressure would be at the outer limit of what would be considered to be a designed range of operating pressures. Catheter balloons, particularly in the size ranges of the graft diameters described by the present application, only infrequently exceed 20 atmospheres (300 psi) of inflation pressure and 30 atmospheres (450 psi) is the highest the applicants are aware of. By changing in diameter only about 1% over this range of pressures, these

grafts made generally as taught by the Myers et al. reference clearly do not anticipate the tubular device of the present claims.

These results are entirely consistent with the statements made in the previously submitted Declaration of James D. Lewis, Ph.D. Applicants submit that they have met the burden of showing that the claimed properties are not present in the graft taught by Myers et al.

II. Claims 1, 5, 20, 22, 23, 26 and 28-31 are rejected under 37 U.S.C. §102(b) as being anticipated by Tu et al. (US 5,061,276).

Tu et al. teach the construction of a vascular graft comprising an inner layer of PTFE and an outer layer of PTFE blended with an elastomer, with the two layers being co-extruded. The Examiner agreed during the interview that claim 1 amended as discussed during the interview would overcome the Tu et al. reference. Claim1 is so amended at this time and as such is not anticipated by Tu et al.

REJECTIONS UNDER 35 U.S.C. §103

I. Claims 6, 7, 9 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Eilentropp (US 4,791,966, hereinafter "Eilentropp").

II. Claim 32 is rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Hughes et al. (US 4,728,328).

III. Claims 3, 4 and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Lee (US 5,123,917).

Claim 1 is amended herein; applicants submit that the amendments overcome the 103 rejections as well as the 102 rejections that are based on Tu et al.

Conclusion

For the foregoing reasons, the present invention is neither taught nor suggested by any of the references of record. Accordingly, Applicants respectfully submit that these claims are now in form for allowance. If further questions remain, Applicants request that the Examiner telephone Applicants' undersigned representative before issuing a further Office Action.

Respectfully submitted,

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